UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,206	10/17/2001	Samuel Achilefu	MRD- 74	5790

26875 7590 02/24/2004

WOOD, HERRON & EVANS, LLP
2700 CAREW TOWER
441 VINE STREET
CINCINNATI, OH 45202

EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/981,206	-	
	Examiner	Art Unit	
	D. L. Jones	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/7/03; 11/10/03; and 2/9/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *8-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the following:

a. Applicant's response filed 10/7/03 traversing the restriction requirement;

b. the supplemental response filed 11/10/03 wherein claims 1-7 were canceled and claim 8 was amended; and

c. the amendment and response filed 2/9/04 wherein a duplicate copy of the documents submitted 11/10/03 was submitted since pages 6 and 7 of the response filed 11/10/03 were missing.

Notes: (1) Claims 8-22 are pending.

(2) In the response filed 11/10/03, Applicant submitted a traversal to the restriction requirement after electing to prosecute the claims directed to a method of performing a diagnostic procedure as set forth in independent claim 8. Applicant traverses the restriction on the grounds that the method claims (claims 8-22) are directed to tandem photodiagnostic and therapeutic applications. The restriction is WITHDRAWN because the supplemental amendment submitted 11/10/03 amended the independent method claim (claim 8) to clearly indicate that the methods are performed tandem.

RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENTS

2. The Applicant's arguments filed 11/10/03 to the rejection of claims 8, 9, and 15-19 made by the Examiner under 35 USC 103 have been fully considered and deemed non-persuasive for the reasons set forth below.

103 Rejection

I. The rejection of claims 8, 9,15-19, and 20 under 35 USC 103(a) as being unpatentable over Licha et al (US Patent No. 6,083,485) is MAINTAINED for reasons of record in the office action mailed 7/8/03 and those set forth below.

Applicant asserts that Licha et al does not disclose tandem photodiagnostic and therapeutic procedures.

Applicant's argument is not persuasive because the tandem photodiagnostic and therapeutic methods only involve administering a composition and 'thereafter performing said tandem diagnostic and therapeutic procedure'. Thus, since Licha et al disclose a composition having the limitations as set forth by Applicant that is administered for diagnostic purposes and there are no therapeutic steps listed by the claim, it is inherent that treatment occurs having administered the compound. Hence, both Licha et al and Applicant have overlapping inventions since they both involve administering a composition encompassed by independent claim 8.

II. The rejection of claims 8, 9,15-19, and 20 under 35 USC 103(a) as being unpatentable over Turner et al (US Patent No. 6,329,531) is MAINTAINED for reasons of record in the office action mailed 7/8/03 and those set forth below.

Applicant's argument is not persuasive because the tandem photodiagnostic and therapeutic methods only involve administering a composition and 'thereafter performing said tandem diagnostic and therapeutic procedure'. Thus, since Turner et al disclose a composition having the limitations as set forth by Applicant that is administered for diagnostic purposes and there are no therapeutic steps listed by the

claim, it is inherent that treatment occurs having administered the compound. Hence, both Turner et al and Applicant have overlapping inventions since they both involve administering a composition encompassed by independent claim 8.

NEW GROUNDS OF REJECTIONS

112 First Paragraph Rejection

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 8-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of diagnosing and therapy of tumors and atherosclerotic plaques and blood clots, does not reasonably provide enablement for all diagnostic and therapeutic methods. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7)

breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The claims are directed to a method of tandem diagnostic and therapeutic methods wherein a composition as set forth in independent claim 1 is encompassed. Support of a diagnostic and therapeutic method directed to tumor and atherosclerotic plaques and blood clots is found on page 11, lines 16-18; page 14, lines 18-24, and page 5, lines 3-7. Also, it should be noted that on page 4, lines 20-24, Applicant asserts that the composition comprises three components: (1) a photoactive agent; (2) a photodiagnostic agent; and (3) *a tumor specific agent*.

(2) State of the prior art

The references do not indicate various methods that are useful with the claimed invention.

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. Independent claim 8 encompasses a vast number of possible diagnostic and therapeutic applications. Applicant's specification does not enable the public to make or use such a vast number of applications.

(4) Level of predictability in the art

The art pertaining to the applications for using Applicant's composition is highly unpredictable. Determining the various diagnostic and therapeutic applications that will be useful with the compositions of the instant invention requires various experimental

procedures and without guidance that is applicable to all diagnostic and therapeutic applications, there would be little predictability in performing the claimed invention.

(5) Amount of direction and guidance provided by the inventor

Independent claim 8 encompasses a vast number of diagnostic and therapeutic applications. Applicant's limited guidance that the compositions are useful for the diagnosis and therapy of tumors and atherosclerotic plaques and blood clots does not enable the public to prepare such a numerous amount of applications wherein the compositions are administered. There is no directional guidance for such methods; hence, there is no enablement for all applications wherein the composition is administered.

(6) Existence of working examples

Independent claim 8 encompasses a vast number of possible diagnostic and therapeutic applications. Applicant's limited working examples do not enable the public to perform such methods. While Applicant's claims encompass a plethora of possible applications, the specification provides only for diagnosing and therapy of tumors and atherosclerotic plaques and blood clots.

(7) Breadth of claims

The claims are extremely broad due to the vast number of possible applications wherein the compositions may be administered to a subject.

(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

112 Second Paragraph Rejection

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 8-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8-22: The claims as written are ambiguous because one cannot readily ascertain what is being claimed. Specifically, the claims as written read on various diagnostic and therapeutic applications. However, one of ordinary skill in the art would not be able to ascertain what applications are encompassed in the claims as written. Applicant is respectfully requested to clarify the claims in order that one may readily determine what application(s) is/are being claimed.

Claims 8-22: The claims as written are ambiguous because it is unclear what diagnostic (i.e., imaging) and therapeutic steps are required to perform the instant invention. In addition, it is unclear how a therapeutic procedure may be performed if

there is no therapeutic agent attached to the structure. In particular, there is no requirement for a therapeutic agent. For example, Y1, Y2, Z1, Z2, Dm, and Bm are substitutents that may be a phototherapeutic agent or have a phototherapeutic agent linked by other atoms to the core structure. However, none of the four variables are required to be a therapeutic agent according to the claims as written. Thus, the variables Y1, Y2, Z1, and Z2 may all be hydrogen, for example. Similarly, in regards to performing a diagnostic procedure, a diagnostic agent is not a required feature of the claims as written. Furthermore, it is noted that according to Applicant's summary of the invention appearing in the specification, in order for both tandem diagnostic and therapeutic procedures to occur, a phototherapeutic and photodiagnostic agent needs to be present. In addition, when Applicant identifies the components of the composition, it is stated that the third component is a tumor specific agent. Such claim limitations are not consistent with the claims as now written.

COMMENTS/NOTES

7. Since independent claim 8 has been amended to state that the diagnostic and therapeutic procedures are tandem, Applicant is respectfully requested to replace 'procedure' with 'procedures' in the last line of claim 8.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1616

February 12, 2004